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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,899	04/12/2001	Jean-Marc Balloul	032751-052	1686

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EXAMINER	
BROWN, TIMOTHY M	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/832,899	BALLOUL ET AL.	
	Examin r	Art Unit	
	Timothy M. Brown	1648	

-- The MAILING DATE of this communication appears on th cover sh et with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-23* is/are pending in the application.

4a) Of the above claim(s) *7,16,17 and 19-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,8-15 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the Amendment received September 16, 2004. Claim 4 has been cancelled such that claims 1-3 and 5-23 are pending. Claims 7, 16, 17 and 19-23 have been withdrawn and claims 1-3, 5, 6, 8-15 and 18 are under examination.

The status of the claims is as follows: the objection to claim 1 is withdrawn; the objection to claims 4-6, 11-15 and 18 for improper dependency is withdrawn; the rejection of claims 9 and 10 as lacking enablement is withdrawn; and the rejection of claims 1-3 and 8 as anticipated under Pal et al. is withdrawn.

Claim Objections

Claim 9 is objected to for being ungrammatical in that the language "wherein said poxviral particle is an IMV" is redundant. This is because claim 1, from which claim 9 depends, provides that "the poxviral partical is an intracellular mature virus . . . ."

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5, 6, 8-15 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 1 is indefinite in the recitation of "heterologous ligand moiety." This term fails to define the scope of the claim because it unclear whether "heterologous ligand

moiety" refers to a chimeric protein, or a single protein that has been modified such as by glycosylation, farnesylation, or the addition of some other member. Providing that the ligand is "heterologous" simply indicates that it has different components, but the nature of these components is undefined. Thus, the term "heterologous ligand moiety" fails to define the nature of the claimed poxviral particle.

Independent claim 1 is also indefinite in providing that the heterologous ligand moiety is "capable of binding an anti-ligand molecule." Applicants' use of "capable of" does not make it clear whether the claim requires the heterologous ligand moiety to bind the antiligand with specificity. That is, any ligand that is simply "capable" of binding an anti-ligand molecule is not necessarily specific for that molecule – non-specific molecular forces make it possible for ligands to interact with other non-anti-ligand molecules. Thus, Applicants' use of "capable of" fails to particularly point out and distinctly claim the scope of the invention. Note this indefinite use of "capable of" also appears in claims 5 and 6.

Claim 5 is indefinite in the recitation of "capable of" as discussed under claim 1. Claim 5 is further indefinite in providing that the "heterologous ligand moiety is capable of binding . . . a cellular protein differentially or overexpressed" on tumor cells. It is unclear how a cellular protein that is differentially or overexpressed may serve as an anti-ligand for targeting tumor cells when normal cells would also express the cellular protein, albeit at different levels.

Claim 8 is indefinite in the recitation of "wherein said heterologous ligand moiety is a polypeptide and wherein it . . . ." The use of "it" in this context renders the claim indefinite because it is unclear whether "it" refers to the antecedent polypeptide, or some other noun in the

claim. Amending the claim to recite "wherein said heterologous ligand moiety is a polypeptide and wherein said polypeptide . . . ." would overcome this rejection.

Claim 11 is similarly indefinite in the recitation of "wherein said heterologous ligand moiety comprises a signal peptide facilitating its insertion." The use of "its" is indefinite because it is unclear whether "its" refers to the heterologous ligand in its entirety, or just the signal peptide. Amending the claim to recite "a signal peptide facilitating said signal peptide's insertion" would overcome this rejection.

Claim 11 is indefinite in the recitation of "wherein said heterologous ligand moiety comprises a signal peptide facilitating its insertion in the envelope of said poxviral particle." This language simply refers to the physical properties of the heterologous ligand moiety. Providing that the signal peptide facilitates the insertion of the heterologous ligand moiety into the viral envelope does not define the physical characteristics of the signal peptide. Thus, one of ordinary skill in the art would not know what type of peptides fall within the scope of the claim.

Claim 12 is also indefinite for attempting to define the heterologous ligand moiety by its properties. Claim 12 states that the "signal peptide allows the translocation of said heterologous ligand moiety in the trans-Golgi network. As with claim 11, setting out how the heterologous ligand moiety behaves in a cell does not describe the ligand's physical characteristics one skilled in the art. Therefore, claim 12 is indefinite.

Claim 13 is indefinite in the recitation of "wherein said signal peptide is derived from . . . TGN51 ." The use of "derived from" is indefinite because it is unclear what changes can be made to "derive" a signal peptide from TGN51. One skilled in the art would not know

"deriving" the signal peptide is derived from TGN51 involves truncation, glycosylation, farnesylation, linearizing or cross-linking. Thus, the scope of claim 13 is indefinite.

Claim 15 is indefinite in that the recitation of "suicide gene" fails to define the claimed polynucleotide with particularity. The term "suicide gene" lacks a clear and definite meaning in the art and the specification fails to provide any description that clarifies the term as it is used in the claim. There is no indication of such a gene's sequence, or the proteins that qualify as being encoded by such a gene. Thus, the term "suicide gene" renders claim 15 indefinite.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 6, 8-15 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable one skilled in the art to practice the full scope of the claimed invention without undue experimentation. The specification enables an IMV poxvirus, wherein the infection specificity is conferred by a heterologous ligand moiety *comprising the expression product of the A27L gene.* The specification does not enable one skilled in the art to make and use, without undue experimentation, an IMV poxvirus particle having infection specificity that "is conferred by at least one heterologous ligand moiety which is localized at the surface of said poxviral particle."

Undue experimentation is defined by a number of factors including: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the

level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

Here, the breadth of the claims provides that the "heterologous ligand moiety" may comprise any ligand that has different components, and is capable of binding a target cell ligand. Thus, the claims read on a broad range of potential targeting molecules. Although the level of skill in the art is high, conjugating targeting ligands to poxviral proteins, let alone proteins of the IMV, is an unpredictable science. This is because poxviral targeting ligands must include specific targeting features in order for the targeting ligand to be exposed on the surface of infectious IMV particles. Research by Gomez et al. shows that this vital signaling function is carried out by the protein of the A27L gene (i.e. p14) (Gomez, C.E. Arch Virol (2001) 146, pp 875-892). Consistent with these findings, Applicants' specification only teaches a targeting ligand that comprises a heterologous p14 polypeptide. The specification provides no working example, or other teaching, that demonstrates how one skilled in the art might produce a heterologous targeting ligand that omits the signaling moiety of the p14 polypeptide. Based on the unpredictability noted above, and the lack of direction for producing the range of targeting moieties claimed, undue experimentation would be required in order for one skilled in the art the art to make and the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb

James C. Housel

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